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ETHICON, INC., and  
JOHNSON & JOHNSON

**UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA  
SOUTHERN DIVISION**

JULIE CRUZ and RAY CRUZ,

Plaintiffs,

v.

JOHNSON & JOHNSON, INC.;  
ETHICON, INC.; and COLOPLAST  
CORP.,

Defendants.

CASE NO.: 8:18-cv-01539-JVS-JDE

**ANSWER AND DEFENSES OF  
DEFENDANT ETHICON, INC. TO  
PLAINTIFFS' FIRST AMENDED  
COMPLAINT; DEMAND FOR JURY  
TRIAL**

The Honorable James V. Selna  
Courtroom: 10C (Santa Ana)

Defendant Ethicon, Inc. ("Ethicon"), by and through its attorneys, responds to  
Plaintiffs' Complaint ("Complaint") as follows.

**RESPONSE TO "NATURE OF ACTION"<sup>1</sup>**

1. Ethicon lacks sufficient knowledge or information to know whether Plaintiff  
Julie Cruz was treated with any of its products; therefore, Ethicon denies that allegation.  
Ethicon denies the remaining allegations contained in Paragraph 1 of Plaintiffs'  
Complaint.

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<sup>1</sup> The repetition of the Complaint's subheadings is done solely for organizational purposes and is  
not an admission as to their truth.

**RESPONSE TO “PARTIES”**

2. Ethicon is without sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in the first sentence of Paragraph 2 of Plaintiffs’ Complaint, and, therefore, Ethicon denies those allegations. Ethicon denies the remaining allegations contained in Paragraph 2 of Plaintiffs’ Complaint.

3. Ethicon admits that Johnson & Johnson is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey, and admits that Johnson & Johnson’s website speaks for itself. Ethicon further admits that it developed, manufactured, tested, marketed, promoted, distributed and sold certain pelvic mesh products for uses consistent with the packaging and labeling. Johnson & Johnson does not develop, manufacture, test, market, promote, distribute or sell any product. Ethicon denies the remaining allegations contained in Paragraph 3 of Plaintiffs’ Complaint.

4. Ethicon admits that it is a New Jersey corporation with its principal place of business in Somerville, New Jersey, and that it is a subsidiary of Johnson & Johnson. Ethicon denies the remaining allegations contained in Paragraph 4 of Plaintiffs’ Complaint.

5. Paragraph 5 of Plaintiffs’ Complaint makes no allegations against Ethicon and requires no response by Ethicon. To the extent a response is required, Ethicon is without sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 5 of Plaintiffs’ Complaint, and, therefore, denies those allegations.

**RESPONSE TO “JURISDICTION AND VENUE”**

6. Paragraph 6 of Plaintiffs’ Complaint states a legal conclusion and requires no response by Ethicon. To the extent a response is required, Ethicon is without sufficient knowledge or information so as for form a belief as to the truth of the allegations contained in Paragraph 6 of Plaintiffs’ Complaint, and, therefore, denies those factual allegations and legal conclusion.

7. The first sentence of Paragraph 7 of Plaintiffs' Complaint states a legal conclusion and requires no response by Ethicon. To the extent a response is required, Ethicon is without sufficient knowledge or information to form a belief as to the truth of the allegations contained in the first sentence of Paragraph 7, and, therefore, denies those allegations. As to the second sentence of Paragraph 7, Ethicon admits only that it sold certain pelvic mesh products for uses consistent with the packaging and labeling, and that they have been available for purchase in the State of California. Johnson & Johnson does not sell any product. Ethicon denies the remaining allegations contained in Paragraph 7 of Plaintiffs' Complaint.

8. Ethicon denies the allegations contained in Paragraph 8 of Plaintiffs' Complaint.

9. Ethicon admits only that it developed certain pelvic mesh products for uses consistent with the packaging and labeling. Johnson & Johnson does not develop any product. Ethicon denies the remaining allegations contained in Paragraph 9 of Plaintiffs' Complaint.

10. Ethicon admits only that it designed, manufactured, marketed, promoted, and sold certain pelvic mesh products, including but not limited to Gynecare TVT Obturator System (hereinafter "TVT-O"), for uses consistent with the packaging and labeling, and that they been available for purchase in the State of California. Johnson & Johnson does not design, manufacture, label, package, market, advertise, promote or sell any product. Ethicon denies the remaining allegations contained in Paragraph 10 of Plaintiffs' Complaint.

11. Ethicon admits only that it designed and manufactured TVT-O for uses consistent with the packaging and labeling. Johnson & Johnson does not design or manufacture any product. Ethicon lacks sufficient knowledge or information to know whether Plaintiff Julie Cruz was treated with any of its products, and Ethicon denies that allegation. Ethicon denies the remaining allegations contained in Paragraph 11 of Plaintiffs' Complaint.

1           12. Ethicon admits only that it sold TVT-O for uses consistent with the  
2 packaging and labeling. Johnson & Johnson does not sell any product. Ethicon lacks  
3 sufficient knowledge or information to know whether Plaintiff Julie Cruz was treated  
4 with any of its products, and Ethicon denies that allegation. Ethicon denies the remaining  
5 allegations contained in Paragraph 12 of Plaintiffs' Complaint.

6           13. Ethicon admits only that it sold TVT-O for uses consistent with the  
7 packaging and labeling. Johnson & Johnson does not sell any product. Ethicon lacks  
8 sufficient knowledge or information to know whether Plaintiff Julie Cruz was treated  
9 with any of its products, and Ethicon denies that allegation. Ethicon denies the remaining  
10 allegations contained in Paragraph 13 of Plaintiffs' Complaint.

11           14. Ethicon admits only that it sold TVT-O for uses consistent with the  
12 packaging and labeling, and that it has been available for purchase in the United States,  
13 including the State of California. Johnson & Johnson does not design or manufacture any  
14 product. Ethicon denies the remaining allegation contained in Paragraph 14 of Plaintiffs'  
15 Complaint.

16           15. Paragraph 15 of Plaintiffs' Complaint makes no allegations against Ethicon  
17 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
18 without sufficient knowledge or information so as to form a belief as to the truth of the  
19 allegations contained in Paragraph 15 of Plaintiffs' Complaint, and, therefore, denies  
20 those allegations.

21           16. Paragraph 16 of Plaintiffs' Complaint makes no allegations against Ethicon  
22 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
23 without sufficient knowledge or information so as to form a belief as to the truth of the  
24 allegations contained in Paragraph 16 of Plaintiffs' Complaint, and, therefore, denies  
25 those allegations.

26           17. Paragraph 17 of Plaintiffs' Complaint makes no allegations against Ethicon  
27 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
28 without sufficient knowledge or information so as to form a belief as to the truth of the

1 allegations contained in Paragraph 17 of Plaintiffs' Complaint, and, therefore, denies  
2 those allegations.

3 18. Paragraph 18 of Plaintiffs' Complaint makes no allegations against Ethicon  
4 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
5 without sufficient knowledge or information so as to form a belief as to the truth of the  
6 allegations contained in Paragraph 18 of Plaintiffs' Complaint, and, therefore, denies  
7 those allegations.

8 19. Paragraph 19 of Plaintiffs' Complaint makes no allegations against Ethicon  
9 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
10 without sufficient knowledge or information so as to form a belief as to the truth of the  
11 allegations contained in Paragraph 19 of Plaintiffs' Complaint, and, therefore, denies  
12 those allegations.

13 20. Paragraph 20 of Plaintiffs' Complaint makes no allegations against Ethicon  
14 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
15 without sufficient knowledge or information so as to form a belief as to the truth of the  
16 allegations contained in Paragraph 20 of Plaintiffs' Complaint, and, therefore, denies  
17 those allegations.

18 21. Paragraph 21 of Plaintiffs' Complaint makes no allegations against Ethicon  
19 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
20 without sufficient knowledge or information so as to form a belief as to the truth of the  
21 allegations contained in Paragraph 21 of Plaintiffs' Complaint, and, therefore, denies  
22 those allegations.

23 22. Paragraph 22 of Plaintiffs' Complaint makes no allegations against Ethicon  
24 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
25 without sufficient knowledge or information so as to form a belief as to the truth of the  
26 allegations contained in Paragraph 22 of Plaintiffs' Complaint, and, therefore, denies  
27 those allegations.  
28

23. Paragraph 23 of Plaintiffs' Complaint states a legal conclusion and requires no response by Ethicon. To the extent a response is required, Ethicon is without sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 23 of Plaintiffs' Complaint, and, therefore, denies those factual allegations and legal conclusion.

24. Ethicon admits only that it sold certain pelvic mesh products for uses consistent with the packaging and labeling, and that they have been available for purchase in the State of California. Johnson & Johnson does not sell any product. Ethicon denies the remaining allegations contained in Paragraph 24 of Plaintiffs' Complaint.

25. Paragraph 25 of Plaintiffs' Complaint states a legal conclusion and requires no response by Ethicon. To the extent a response is required, Ethicon is without sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 25 of Plaintiffs' Complaint, and, therefore, denies those factual allegations and legal conclusion.

26. Paragraph 26 of Plaintiffs' Complaint states a legal conclusion and requires no response by Ethicon. To the extent a response is required, Ethicon denies the factual allegations and legal conclusion contained in Paragraph 26 of Plaintiffs' Complaint.

27. As to the first sentence of Paragraph 27 of Plaintiffs' Complaint, Ethicon admits only that it sold certain pelvic mesh products for uses consistent with the packaging and labeling, and that they have been available for purchase in the State of California. Johnson & Johnson does not sell any product. The second sentence of Paragraph 27 of Plaintiffs' Complaint states a legal conclusion and requires no response by Ethicon. To the extent a response is required, Ethicon is without sufficient knowledge or information so as to form a belief as to those allegations contained in the second sentence of Paragraph 27 of Plaintiffs' Complaint, and, therefore, denies those factual allegations and legal conclusion. Ethicon denies the remaining allegations contained in Paragraph 27 of Plaintiffs' Complaint.

1           28. Paragraph 28 of Plaintiffs' Complaint states a legal conclusion and requires  
2 no response by Ethicon. To the extent a response is required, Ethicon is without sufficient  
3 knowledge or information so as to form a belief as to the truth of the allegations  
4 contained in Paragraph 28 of Plaintiffs' Complaint, and, therefore, denies those factual  
5 allegations and legal conclusion.

6                           **RESPONSE TO "FACTUAL BACKGROUND"**

7           **A. As Against Johnson & Johnson and Ethicon**

8           29. Ethicon is without sufficient knowledge or information so as to form a belief  
9 as to the truth of the allegations contained in Paragraph 29 of Plaintiffs' Complaint, and,  
10 therefore, denies those allegations.

11           30. Ethicon admits only that it manufactured TVT-O for uses consistent with the  
12 packaging and labeling. Johnson & Johnson does not manufacture any product. Ethicon  
13 denies the remaining allegations contained in Paragraph 30 of Plaintiffs' Complaint.

14           31. Ethicon admits only that it manufactured TVT-O for uses consistent with the  
15 packaging and labeling. Johnson & Johnson does not manufacture any product. Ethicon  
16 denies the remaining allegations contained in Paragraph 31 of Plaintiffs' Complaint.

17           32. Ethicon admits only that it designed, marketed, and sold TVT-O for uses  
18 consistent with the packaging and labeling. Johnson & Johnson does not design, market  
19 or sell any product. Ethicon lacks sufficient knowledge or information to know whether  
20 Plaintiff Julie Cruz was treated with any of its products, and Ethicon denies that  
21 allegation. Ethicon denies the remaining allegations contained in Paragraph 32 of  
22 Plaintiffs' Complaint.

23           33. Ethicon admits only that it designed, manufactured, marketed, and sold  
24 certain pelvic mesh products, including but not limited to TVT-O, for uses consistent  
25 with the packaging and labeling. Johnson & Johnson does not design, manufacture,  
26 package, label, market, or sell any product. Ethicon lacks sufficient knowledge or  
27 information to know whether Plaintiff Julie Cruz was treated with any of its products, and  
28



1 Ethicon denies that allegation. Ethicon denies the remaining allegations contained in  
2 Paragraph 33 of Plaintiffs' Complaint.

3 34. Ethicon admits only that it designed TVT-O for uses consistent with the  
4 packaging and labeling. Johnson & Johnson does not design any product. Ethicon lacks  
5 sufficient knowledge or information to know whether Plaintiff Julie Cruz was treated  
6 with any of its products, and Ethicon denies that allegation. Ethicon denies the remaining  
7 allegations contained in Paragraph 34 of Plaintiffs' Complaint.

8 35. Ethicon admits only that it marketed TVT-O for uses consistent with the  
9 packaging and labeling. Johnson & Johnson does not market any product. Ethicon lacks  
10 sufficient knowledge or information to know whether Plaintiff Julie Cruz was treated  
11 with any of its products, and Ethicon denies that allegation. Ethicon denies the remaining  
12 allegations contained in Paragraph 35 of Plaintiffs' Complaint.

13 36. Ethicon admits only that it marketed and promoted TVT-O for uses  
14 consistent with the packaging and labeling, and that it has been available for purchase in  
15 the United States including the State of California. Johnson & Johnson does not market  
16 or promote any product. Ethicon lacks sufficient knowledge or information to know  
17 whether Plaintiff Julie Cruz was treated with any of its products, and Ethicon denies that  
18 allegation. Ethicon denies the remaining allegations contained in Paragraph 36 of  
19 Plaintiffs' Complaint.

20 37. Ethicon admits only that it sold TVT-O for uses consistent with the  
21 packaging and labeling. Johnson & Johnson does not sell any product. Ethicon lacks  
22 sufficient knowledge or information to know whether Plaintiff Julie Cruz was treated  
23 with any of its products, and Ethicon denies that allegation. Ethicon denies the remaining  
24 allegations contained in Paragraph 37 of Plaintiffs' Complaint.

25 38. Ethicon admits only that it sold TVT-O for uses consistent with the  
26 packaging and labeling. Johnson & Johnson does not sell any product. Ethicon denies the  
27 remaining allegations contained in Paragraph 38 of Plaintiffs' Complaint.  
28



1           39. Ethicon admits only that it sold TVT-O for uses consistent with the  
2 packaging and labeling. Johnson & Johnson does not sell any product. Ethicon denies the  
3 remaining allegations contained in Paragraph 39 of Plaintiffs' Complaint.

4           40. Ethicon admits only that it sold TVT-O for uses consistent with the  
5 packaging and labeling, and that it has been available for purchase in the United States  
6 including the State of California. Johnson & Johnson does not sell any product. Ethicon  
7 denies the remaining allegations contained in Paragraph 40 of Plaintiffs' Complaint.

8           41. Paragraph 41 of Plaintiffs' Complaint makes no allegation against Ethicon  
9 and requires no response by Ethicon.

10          42. Paragraph 42 of Plaintiffs' Complaint makes no allegation against Ethicon  
11 and requires no response by Ethicon.

12          43. Paragraph 43 of Plaintiffs' Complaint makes no allegation against Ethicon  
13 and requires no response by Ethicon. To the extent a response is required, Ethicon admits  
14 only that it marketed TVT-O for uses consistent with the packaging and labeling. Johnson  
15 & Johnson does not market any product. Ethicon denies the remaining allegations  
16 contained in Paragraph 43 of Plaintiffs' Complaint as phrased.

17          44. Paragraph 44 of Plaintiffs' Complaint makes no allegation against Ethicon  
18 and requires no response by Ethicon. To the extent a response is required, Ethicon denies  
19 the allegations contained in Paragraph 44 of Plaintiffs' Complaint.

20          45. Ethicon admits that it manufactured TVT-O for uses consistent with the  
21 packaging and labeling, and that it has been classified by the FDA as a regulatory Class II  
22 device. Johnson & Johnson does not manufacture any product. Ethicon denies the  
23 remaining allegations contained in Paragraph 45 of Plaintiffs' Complaint.

24          46. Ethicon admits that the FDA cleared TVT-O under the 510(k) Premarket  
25 Notification. Ethicon denies the remaining allegations contained in Paragraph 46 of  
26 Plaintiffs' Complaint.

27          47. Ethicon denies the allegations contained in Paragraph 47 of Plaintiffs'  
28 Complaint.

1           48.   Ethicon lacks sufficient knowledge to know whether Plaintiff Julie Cruz was  
2 treated with any of its products, and Ethicon denies that allegation. Ethicon denies the  
3 remaining allegations contained in Paragraph 48 of Plaintiffs' Complaint.

4           **B.    As Against Coloplast**

5           49.   Paragraphs 49 through 64 of Plaintiffs' Complaint make no allegations  
6 against Ethicon and require not response by Ethicon. To the extent a response is required,  
7 Ethicon is without sufficient knowledge or information so as to form a belief as to the  
8 truth of the allegations contained in these paragraphs, and, therefore, denies those  
9 allegations.

10          **C.    Facts Common to All Defendants**

11          65.   Paragraph 65 of Plaintiffs' Complaint makes no allegations against Ethicon  
12 and requires no response by Ethicon. To the extent a response is required, Ethicon admits  
13 that it marketed TVT-O for uses consistent with the packaging and labeling, and that it is  
14 safe and effective for uses consistent with the packaging and labeling. Johnson &  
15 Johnson does not market any product. Ethicon is without sufficient knowledge or  
16 information so as to form a belief as to the truth of the remaining allegations contained in  
17 Paragraph 65 of Plaintiffs' Complaint, and, therefore, Ethicon denies those allegations.

18          66.   Paragraph 66 of Plaintiffs' Complaint makes no allegations against Ethicon  
19 and requires no response by Ethicon. To the extent a response is required, Ethicon admits  
20 only that the July 13, 2011 FDA Safety Communication speaks for itself. Ethicon denies  
21 any remaining allegations contained in Paragraph 66 of Plaintiffs' Complaint.

22          67.   Paragraph 67 of Plaintiffs' Complaint makes no allegations against Ethicon  
23 and requires no response by Ethicon. To the extent a response is required, Ethicon admits  
24 only that the July 13, 2011 FDA Safety Communication speaks for itself. Ethicon denies  
25 any remaining allegations contained in Paragraph 67 of Plaintiffs' Complaint.

26          68.   Paragraph 68 of Plaintiffs' Complaint makes no allegations against Ethicon  
27 and requires no response by Ethicon. To the extent a response is required, Ethicon admits  
28

1 only that the July 13, 2011 FDA Safety Communication speaks for itself. Ethicon denies  
2 the remaining allegations contained in Paragraph 68 of Plaintiffs' Complaint.

3 69. Paragraph 69 of Plaintiffs' Complaint makes no allegations against Ethicon  
4 and requires no response by Ethicon. To the extent a response is required, Ethicon admits  
5 only that the July 13, 2011 FDA Safety Communication speaks for itself. Ethicon denies  
6 any remaining allegations contained in Paragraph 69 of Plaintiffs' Complaint.

7 70. Paragraph 70 of Plaintiffs' Complaint makes no allegations against Ethicon  
8 and requires no response by Ethicon. To the extent a response is required, Ethicon admits  
9 only that the referenced publication speaks for itself. Ethicon denies any remaining  
10 allegations contained in Paragraph 70 of Plaintiffs' Complaint.

11 71. Paragraph 71 of Plaintiffs' Complaint makes no allegations against Ethicon  
12 and requires no response by Ethicon. To the extent a response is required, Ethicon admits  
13 only that the referenced publication speaks for itself. Ethicon denies any remaining  
14 allegations contained in Paragraph 71 of Plaintiffs' Complaint.

15 72. Paragraph 72 of Plaintiffs' Complaint makes no allegations against Ethicon  
16 and requires no response by Ethicon. To the extent a response is required, Ethicon admits  
17 only that the referenced publication speaks for itself. Ethicon denies any remaining  
18 allegations contained in Paragraph 72 of Plaintiffs' Complaint.

19 73. Paragraph 73 of Plaintiffs' Complaint makes no allegations against Ethicon  
20 and requires no response by Ethicon. To the extent a response is required, Ethicon admits  
21 only that the referenced publication speaks for itself. Ethicon denies any remaining  
22 allegations contained in Paragraph 73 of Plaintiffs' Complaint.

23 74. Paragraph 74 of Plaintiffs' Complaint makes no allegations against Ethicon  
24 and requires no response by Ethicon. To the extent a response is required, Ethicon admits  
25 only that the referenced publication speaks for itself. Ethicon denies any remaining  
26 allegations contained in Paragraph 74 of Plaintiffs' Complaint.

27 75. Ethicon denies the allegations contained in Paragraph 75 of Plaintiffs'  
28 Complaint.

1           76.    Ethicon denies the allegations contained in Paragraph 76 of Plaintiffs'  
2 Complaint.

3           77.    Ethicon lacks sufficient knowledge or information to know whether Plaintiff  
4 Julie Cruz was treated with any of its products, and, Ethicon denies that allegation.  
5 Ethicon denies the remaining allegations contained in Paragraph 77 of Plaintiffs'  
6 Complaint.

7           78.    Ethicon denies the allegations contained in Paragraph 78 of Plaintiffs'  
8 Complaint.

9           79.    The first two sentences of Paragraph 79 of Plaintiffs' Complaint make no  
10 allegations against Ethicon and requires no response by Ethicon. To the extent a response  
11 is required, Ethicon admits that the FDA's website speaks for itself. Ethicon denies the  
12 remaining allegations contained in Paragraph 79 of Plaintiffs' Complaint.

13           80.    Ethicon denies the allegations contained in Paragraph 80 of Plaintiffs'  
14 Complaint.

15           81.    Ethicon denies the allegation contained in Paragraph 81 of Plaintiffs'  
16 Complaint.

17           82.    Ethicon admits only that it marketed TVT-O for uses consistent with the  
18 packaging and labeling, and that it is safe and effective for uses consistent with the  
19 packaging and labeling. Johnson & Johnson does not market any product. Ethicon denies  
20 the remaining allegations contained in Paragraph 82 of Plaintiffs' Complaint.

21           83.    Ethicon admits that it promoted, marketed, sold and distributed TVT-O for  
22 uses consistent with the packaging and labeling, and that it is safe and effective for uses  
23 consistent with the packaging and labeling. Johnson & Johnson does not advertise,  
24 promote, market, sell or distribute any product. Ethicon lacks sufficient knowledge or  
25 information to know whether Plaintiff Julie Cruz was treated with any of its products, and  
26 Ethicon denies that allegation. Ethicon denies the remaining allegations contained  
27 Paragraph 83 Plaintiffs' Complaint.  
28

84. Ethicon lacks sufficient knowledge or information to know whether Plaintiff Julie Cruz was treated with any of its products, and Ethicon denies that allegation. Ethicon denies the remaining allegations contained in Paragraph 84 of Plaintiffs' Complaint.

85. Ethicon denies the allegations contained in Paragraph 85 of Plaintiffs' Complaint, including subparts (a.) – (l.)

86. Ethicon denies the allegations contained in Paragraph 86 of Plaintiffs' Complaint, including subparts (m.) – (dd.).

87. Ethicon denies the allegations contained in Paragraph 87 of Plaintiffs' Complaint.

88. Ethicon denies the allegations contained in Paragraph 88 of Plaintiffs' Complaint.

89. Ethicon denies the allegations contained Paragraph 89 of Plaintiffs' Complaint.

90. Ethicon denies the allegations contained in Paragraph 90 of Plaintiffs' Complaint.

91. Ethicon admits only that it sold TVT-O for uses consistent with the packaging and labeling. Johnson & Johnson does not sell any product. Ethicon denies the remaining allegations contained in Paragraph 91 of Plaintiffs' Complaint.

92. Ethicon denies the allegations contained in Paragraph 92 of Plaintiffs' Complaint.

93. Ethicon admits only that it sold TVT-O for uses consistent with the packaging and labeling. Johnson & Johnson does not sell any product. Ethicon lacks sufficient knowledge or information to know whether Plaintiff Julie Cruz was treated with any of its products, and Ethicon denies that allegation. Ethicon denies the remaining allegations contained in Paragraph 93 of Plaintiffs' Complaint.

94. Ethicon denies the allegations contained in Paragraph 94 of Plaintiffs' Complaint.

95. Ethicon denies the allegations contained in Paragraph 95 of Plaintiffs' Complaint.

96. Ethicon lacks sufficient knowledge or information to know whether Plaintiff Julie Cruz was treated with any of its products, and Ethicon denies that allegation. Ethicon denies the remaining allegations contained in Paragraph 96 of Plaintiffs' Complaint.

97. Ethicon denies the allegations contained in Paragraph 97 of Plaintiffs' Complaint.

98. Ethicon admits that it promoted TVT-O for uses consistent with the packaging and labeling, and that it is safe and effective for uses consistent with the packaging and labeling. Johnson & Johnson does not promote any product. Ethicon denies the remaining allegations contained in Paragraph 98 of Plaintiffs' Complaint.

99. Ethicon denies the allegations contained in Paragraph 99 of Plaintiffs' Complaint.

100. Ethicon denies the allegations contained in Paragraph 100 Plaintiffs' Complaint.

101. Ethicon denies the allegations contained in Paragraph 101 Plaintiffs' Complaint.

102. Ethicon lacks sufficient knowledge or information to know whether Plaintiff Julie Cruz was treated with any of its products, and Ethicon denies that allegation. Ethicon denies the remaining allegations contained in Paragraph 102 Plaintiffs' Complaint.

## **RESPONSE TO "CAUSES OF ACTION:**

### **COUNT I: NEGLIGENCE"**

103. Ethicon incorporates by reference its responses to each and every allegation contained in Plaintiffs' Complaint.

104. Ethicon admits that it has certain duties imposed on it by law, but denies that it breached any duty. Ethicon admits that it designed, manufactured, marketed, and sold

1 TVT-O for uses consistent with the packaging and labeling. Johnson & Johnson does not  
2 design, manufacture, market, package, label, or sell any product. Ethicon denies the  
3 remaining allegations contained in Paragraph 104 of Plaintiffs' Complaint.

4 105. Ethicon denies the allegations contained in Paragraph 105 of Plaintiffs'  
5 Complaint, including the bulleted subparts.

6 106. Paragraph 106 of Plaintiffs' Complaint makes no allegations against Ethicon  
7 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
8 without sufficient knowledge or information so as to form a belief as to the truth of the  
9 allegations contained in Paragraph 106 of Plaintiffs' Complaint, and, therefore, Ethicon  
10 denies those allegations.

11 107. Paragraph 107 of Plaintiffs' Complaint makes no allegations against Ethicon  
12 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
13 without sufficient knowledge or information so as to form a belief as to the truth of the  
14 allegations contained in Paragraph 107 of Plaintiffs' Complaint, and, therefore, Ethicon  
15 denies those allegations.

16 108. Ethicon denies the allegations contained in Paragraph 108 of Plaintiffs'  
17 Complaint, including the bulleted subparts.

18 **RESPONSE TO "COUNT II:**

19 **STRICT LIABILITY: MANUFACTURING DEFECT"**

20 109. Ethicon incorporates by reference its responses to each and every allegation  
21 contained in Plaintiffs' Complaint.

22 110. Ethicon lacks sufficient knowledge or information to know whether Plaintiff  
23 Julie Cruz was treated with any of its products, and Ethicon denies that allegation.  
24 Ethicon denies the remaining allegations contained in Paragraph 110 of Plaintiffs'  
25 Complaint.

26 111. Paragraph 111 of Plaintiffs' Complaint makes no allegations against Ethicon  
27 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
28 without sufficient knowledge or information so as to form a belief as to the truth of the



1 allegations contained in Paragraph 111 of Plaintiffs' Complaint, and, therefore, Ethicon  
2 denies those allegations.

3 112. Ethicon denies the allegations contained in Paragraph 112 of Plaintiffs'  
4 Complaint.

5 113. Ethicon denies the allegations contained in Paragraph 113 of Plaintiffs'  
6 Complaint.

7 **RESPONSE TO "COUNT III:**

8 **STRICT LIABILITY:FAILURE TO WARN"**

9 114. Ethicon incorporates by reference its responses to each and every allegation  
10 contained in Plaintiffs' Complaint.

11 115. Ethicon lacks sufficient knowledge or information to know whether Plaintiff  
12 Julie Cruz was treated with any of its products, and Ethicon denies that allegation.  
13 Ethicon denies the remaining allegations contained in Paragraph 115 of Plaintiffs'  
14 Complaint, including the bulleted subparts.

15 116. Paragraph 116 of Plaintiffs' Complaint makes no allegations against Ethicon  
16 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
17 without sufficient knowledge or information so as to form a belief as to the truth of the  
18 allegations contained in Paragraph 116 of Plaintiffs' Complaint, and, therefore, Ethicon  
19 denies those allegations.

20 117. Ethicon denies the allegations contained in Paragraph 117 of Plaintiffs'  
21 Complaint.

22 118. Ethicon denies the allegations contained in Paragraph 118 of Plaintiffs'  
23 Complaint.

24 **RESPONSE TO "COUNT IV:**

25 **FRAUDULENT CONCEALMENT"**

26 119. Ethicon incorporates by reference its responses to each and every allegation  
27 contained in Plaintiffs' Complaint.  
28

1           120. Ethicon admits that TVT-O is safe and effective for uses consistent with the  
2 packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph  
3 120 of Plaintiffs' Complaint.

4           121. Paragraph 121 of Plaintiffs' Complaint makes no allegations against Ethicon  
5 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
6 without sufficient knowledge or information so as to form a belief as to the truth of the  
7 allegations contained in Paragraph 121 of Plaintiffs' Complaint, and, therefore, Ethicon  
8 denies those allegations.

9           122. Ethicon denies the allegations contained in Paragraph 122 of Plaintiffs'  
10 Complaint.

11           123. Ethicon admits it has certain duties imposed on it by law, but denies that it  
12 breached any duty. Ethicon denies the remaining allegations contained in Paragraph 123  
13 of Plaintiffs' Complaint.

14           124. Ethicon lacks sufficient knowledge or information to know whether Plaintiff  
15 Julie Cruz was treated with any of its products, and Ethicon denies that allegation.  
16 Ethicon denies the remaining allegations contained in Paragraph 124 of Plaintiffs'  
17 Complaint.

18           125. Ethicon denies the allegations contained in Paragraph 125 of Plaintiffs'  
19 Complaint.

20           126. Ethicon denies the allegations contained in Paragraph 126 of Plaintiffs'  
21 Complaint.

22           127. Paragraph 127 of Plaintiffs' Complaint makes no allegations against Ethicon  
23 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
24 without sufficient knowledge or information so as to form a belief as to the truth of the  
25 allegations contained in Paragraph 127 of Plaintiffs' Complaint, and, therefore, Ethicon  
26 denies those allegations.

27           128. Paragraph 128 of Plaintiffs' Complaint makes no allegations against Ethicon  
28 and requires no response by Ethicon. To the extent a response is required, Ethicon is

1 without sufficient knowledge or information so as to form a belief as to the truth of the  
2 allegations contained in Paragraph 128 of Plaintiffs' Complaint, and, therefore, Ethicon  
3 denies those allegations.

4 129. Paragraph 129 of Plaintiffs' Complaint makes no allegations against Ethicon  
5 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
6 without sufficient knowledge or information so as to form a belief as to the truth of the  
7 allegations contained in Paragraph 129 of Plaintiffs' Complaint, and, therefore, Ethicon  
8 denies those allegations.

9 130. Paragraph 130 of Plaintiffs' Complaint makes no allegations against Ethicon  
10 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
11 without sufficient knowledge or information so as to form a belief as to the truth of the  
12 allegations contained in Paragraph 130 of Plaintiffs' Complaint, and, therefore, Ethicon  
13 denies those allegations.

14 131. Ethicon denies the allegations contained in Paragraph 131 of Plaintiffs'  
15 Complaint.

16 132. Ethicon denies the allegations contained in Paragraph 132 of Plaintiffs'  
17 Complaint.

18 133. Ethicon denies the allegations contained in Paragraph 133 of Plaintiffs'  
19 Complaint.

20 **RESPONSE TO "COUNT V:**

21 **CONSTRUCTIVE FRAUD"**

22 134. Ethicon incorporates by reference its responses to each and every allegation  
23 contained in Plaintiffs' Complaint.

24 135. Ethicon denies the allegations contained in Paragraph 135 of Plaintiffs'  
25 Complaint.

26 136. Ethicon denies the allegations contained in Paragraph 136 of Plaintiffs'  
27 Complaint.  
28

1           137. Paragraph 137 of Plaintiffs' Complaint makes no allegations against Ethicon  
2 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
3 without sufficient knowledge or information so as to form a belief as to the truth of the  
4 allegations contained in Paragraph 137 of Plaintiffs' Complaint, and, therefore, denies  
5 those allegations.

6           138. Ethicon denies the allegations contained in Paragraph 138 of Plaintiffs'  
7 Complaint.

8           139. Ethicon denies the allegations contained in Paragraph 139 of Plaintiffs'  
9 Complaint.

10           140. Paragraph 140 of Plaintiffs' Complaint makes no allegations against Ethicon  
11 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
12 without sufficient knowledge or information so as to form a belief as to the truth of the  
13 allegations contained in Paragraph 140 of Plaintiffs' Complaint, and, therefore, denies  
14 those allegations.

15           141. Paragraph 141 of Plaintiffs' Complaint makes no allegations against Ethicon  
16 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
17 without sufficient knowledge or information so as to form a belief as to the truth of the  
18 allegations contained in Paragraph 141 of Plaintiffs' Complaint, and, therefore, denies  
19 those allegations.

20           142. Paragraph 142 of Plaintiffs' Complaint makes no allegations against Ethicon  
21 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
22 without sufficient knowledge or information so as to form a belief as to the truth of the  
23 allegations contained in Paragraph 142 of Plaintiffs' Complaint, and, therefore, denies  
24 those allegations.

25           143. Paragraph 143 of Plaintiffs' Complaint makes no allegations against Ethicon  
26 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
27 without sufficient knowledge or information so as to form a belief as to the truth of the  
28

1 allegations contained in Paragraph 143 of Plaintiffs' Complaint, and, therefore, denies  
2 those allegations.

3 144. Paragraph 144 of Plaintiffs' Complaint makes no allegations against Ethicon  
4 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
5 without sufficient knowledge or information so as to form a belief as to the truth of the  
6 allegations contained in Paragraph 144 of Plaintiffs' Complaint, and, therefore, denies  
7 those allegations.

8 **RESPONSE TO "VI:**  
9 **BREACH OF IMPLIED WARRANTY"**

10 145. Ethicon incorporates by reference its responses to each and every allegation  
11 contained in Plaintiffs' Complaint.

12 146. Ethicon admits that TVT-O is safe and effective for uses consistent with the  
13 packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph  
14 146 of Plaintiffs' Complaint.

15 147. Ethicon lacks sufficient knowledge or information to know whether Plaintiff  
16 Julie Cruz was treated with any of its products, and Ethicon denies that allegation.  
17 Ethicon admits only that it sold TVT-O for uses consistent with the packaging and  
18 labeling. Johnson & Johnson does not sell any product. Ethicon denies the remaining  
19 allegations contained in Paragraph 147 of Plaintiffs' Complaint.

20 148. Ethicon lacks sufficient knowledge or information to know whether Plaintiff  
21 Julie Cruz was treated with any of its products, and Ethicon denies that allegation.  
22 Ethicon denies the remaining allegations contained in Paragraph 148 of Plaintiffs'  
23 Complaint.

24 149. Ethicon denies the allegations contained in Paragraph 149 of Plaintiffs'  
25 Complaint.

26 150. Ethicon lacks sufficient knowledge or information to know whether Plaintiff  
27 Julie Cruz was treated with any of its products, and Ethicon denies that allegation.  
28

1 Ethicon denies the remaining allegations contained in Paragraph 150 of Plaintiffs'  
2 Complaint.

3 151. Paragraph 151 of Plaintiffs' Complaint makes no allegations against Ethicon  
4 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
5 without sufficient knowledge or information so as to form a belief as to the truth of the  
6 allegations contained in Paragraph 151 of Plaintiffs' Complaint, and, therefore, denies  
7 those allegations.

8 152. Paragraph 152 of Plaintiffs' Complaint makes no allegations against Ethicon  
9 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
10 without sufficient knowledge or information so as to form a belief as to the truth of the  
11 allegations contained in Paragraph 152 of Plaintiffs' Complaint, and, therefore, denies  
12 those allegations.

13 153. Paragraph 153 of Plaintiffs' Complaint makes no allegations against Ethicon  
14 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
15 without sufficient knowledge or information so as to form a belief as to the truth of the  
16 allegations contained in Paragraph 153 of Plaintiffs' Complaint, and, therefore, denies  
17 those allegations.

18 154. Paragraph 154 of Plaintiffs' Complaint makes no allegations against Ethicon  
19 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
20 without sufficient knowledge or information so as to form a belief as to the truth of the  
21 allegations contained in Paragraph 154 of Plaintiffs' Complaint, and, therefore, denies  
22 those allegations.

23 155. Paragraph 155 of Plaintiffs' Complaint makes no allegations against Ethicon  
24 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
25 without sufficient knowledge or information so as to form a belief as to the truth of the  
26 allegations contained in Paragraph 155 of Plaintiffs' Complaint, and, therefore, denies  
27 those allegations.  
28

156. Ethicon denies the allegations contained in Paragraph 156 of Plaintiffs' Complaint.

157. Ethicon denies the allegations contained in Paragraph 157 of Plaintiffs' Complaint.

158. Ethicon denies the allegations contained in Paragraph 158 of Plaintiffs' Complaint.

**RESPONSE TO "COUNT VII:**  
**NEGLIGENT MISREPRESENTATION"**

159. Ethicon incorporates by reference its responses to each and every allegation contained in Plaintiffs' Complaint.

160. Ethicon admits that TVT-O is safe and effective for uses consistent with the packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph 160 of Plaintiffs' Complaint.

161. Ethicon denies the allegations contained in Paragraph 161 of Plaintiffs' Complaint.

162. Ethicon admits only that it promoted TVT-O for uses consistent with the packaging and labeling, and that it is safe and effective for uses consistent with the packaging and labeling. Johnson & Johnson does not promote any product. Ethicon denies the remaining allegations contained in Paragraph 162 of Plaintiffs' Complaint.

163. Ethicon denies the allegations contained in Paragraph 163 of Plaintiffs' Complaint.

164. Ethicon lacks sufficient knowledge or information to know whether Plaintiff Julie Cruz was treated with any of its products, and Ethicon denies that allegation. Ethicon denies the remaining allegations contained in Paragraph 164 of Plaintiffs' Complaint.

165. Paragraph 165 of Plaintiffs' Complaint makes no allegations against Ethicon and requires no response by Ethicon. To the extent a response is required, Ethicon is without sufficient knowledge or information so as to form a belief as to the truth of the



1 allegations contained in Paragraph 165 of Plaintiffs' Complaint, and, therefore, denies  
2 those allegations.

3 166. Paragraph 166 of Plaintiffs' Complaint makes no allegations against Ethicon  
4 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
5 without sufficient knowledge or information so as to form a belief as to the truth of the  
6 allegations contained in Paragraph 166 of Plaintiffs' Complaint, and, therefore, denies  
7 those allegations.

8 167. Paragraph 167 of Plaintiffs' Complaint makes no allegations against Ethicon  
9 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
10 without sufficient knowledge or information so as to form a belief as to the truth of the  
11 allegations contained in Paragraph 167 of Plaintiffs' Complaint, and, therefore, denies  
12 those allegations.

13 168. Paragraph 168 of Plaintiffs' Complaint makes no allegations against Ethicon  
14 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
15 without sufficient knowledge or information so as to form a belief as to the truth of the  
16 allegations contained in Paragraph 168 of Plaintiffs' Complaint, and, therefore, denies  
17 those allegations.

18 169. Paragraph 169 of Plaintiffs' Complaint makes no allegations against Ethicon  
19 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
20 without sufficient knowledge or information so as to form a belief as to the truth of the  
21 allegations contained in Paragraph 169 of Plaintiffs' Complaint, and, therefore, denies  
22 those allegations.

23 170. Ethicon denies the allegations contained in Paragraph 170 of Plaintiffs'  
24 Complaint.

25 **RESPONSE TO "COUNT VIII:**

26 **NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS"**

27 171. Ethicon incorporates by reference its responses to each and every allegation  
28 contained in Plaintiffs' Complaint.

172. Ethicon denies the allegations contained in Paragraph 172 of Plaintiffs' Complaint.

173. Ethicon lacks sufficient knowledge or information to know whether Plaintiff Julie Cruz was treated with any of its products, and Ethicon denies that allegation. Ethicon admits only that it sold and distributed TVT-O for uses consistent with the packaging and labeling. Johnson & Johnson does not sell or distribute any product. Ethicon denies the remaining allegations contained in Paragraph 173 of Plaintiffs' Complaint.

174. Paragraph 174 of Plaintiffs' Complaint makes no allegations against Ethicon and requires no response by Ethicon. To the extent a response is required, Ethicon is without sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 174 of Plaintiffs' Complaint, and, therefore, denies those allegations.

175. Paragraph 175 of Plaintiffs' Complaint makes no allegations against Ethicon and requires no response by Ethicon. To the extent a response is required, Ethicon is without sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 175 of Plaintiffs' Complaint, and, therefore, denies those allegations.

176. Ethicon denies the allegations contained in Paragraph 176 of Plaintiffs' Complaint.

**RESPONSE TO "COUNT IX:**  
**BREACH OF EXPRESS WARRANTY"**

177. Ethicon incorporates by reference its responses to each and every allegation contained in Plaintiffs' Complaint.

178. As to the first sentence of Paragraph 178 of Plaintiffs' Complaint, Ethicon admits that TVT-O is safe and effective for uses consistent with the packaging and labeling. The second sentence of Paragraph 178 of Plaintiffs' Complaint makes no allegations against Ethicon and requires no response by Ethicon. To the extent a response

1 is required, Ethicon is without sufficient knowledge or information so as to form a belief  
2 as to the truth of the allegations contained in the second sentence of Paragraph 178 of  
3 Plaintiffs' Complaint. Ethicon denies the remaining allegations contained in Paragraph  
4 178 of Plaintiffs' Complaint.

5 179. Ethicon lacks sufficient knowledge or information to know whether Plaintiff  
6 Julie Cruz was treated with any of its products, and Ethicon denies that allegation.  
7 Ethicon admits only that TVT-O is safe and effective for uses consistent with the  
8 packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph  
9 179 of Plaintiffs' Complaint as they relate to Ethicon.

10 180. Ethicon admits that TVT-O is safe and effective for uses consistent with the  
11 packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph  
12 180 of Plaintiffs' Complaint.

13 181. Ethicon lacks sufficient knowledge or information to know whether Plaintiff  
14 Julie Cruz was treated with any of its products, and Ethicon denies that allegation.  
15 Ethicon denies the remaining allegations contained in Paragraph 181 of Plaintiffs'  
16 Complaint.

17 182. As to the first sentence of Paragraph 182 of Plaintiffs' Complaint, Ethicon  
18 admits that TVT-O is safe and effective for uses consistent with the packaging and  
19 labeling. The second sentence of Paragraph 182 of Plaintiffs' Complaint makes no  
20 allegations against Ethicon and requires no response by Ethicon. To the extent a response  
21 is required, Ethicon is without sufficient knowledge or information so as to form a belief  
22 as to the truth of the allegations contained in the second sentence of Paragraph 182 of  
23 Plaintiffs' Complaint, and, therefore, denies those allegations. Ethicon denies the  
24 remaining allegations contained in Paragraph 182 of Plaintiffs' Complaint.

25 183. Ethicon denies the allegations contained in Paragraph 183 of Plaintiffs'  
26 Complaint.

27 184. Paragraph 184 of Plaintiffs' Complaint makes no allegations against Ethicon  
28 and requires no response by Ethicon. To the extent a response is required, Ethicon is

1 without sufficient knowledge or information so as to form a belief as to the truth of the  
2 allegations contained in Paragraph 184 of Plaintiffs' Complaint, and, therefore, denies  
3 those allegations.

4 185. Ethicon lacks sufficient knowledge or information to know whether Plaintiff  
5 Julie Cruz was treated with any of its products, and Ethicon denies that allegation.  
6 Ethicon admits only that TVT-O is safe and effective for uses consistent with the  
7 packaging and labeling. Ethicon denies the remaining allegations contained in Paragraph  
8 185 of Plaintiffs' Complaint as they relate to Ethicon.

9 186. Ethicon lacks sufficient knowledge or information to know whether Plaintiff  
10 Julie Cruz was treated with any of its products, and Ethicon denies that allegation.  
11 Ethicon denies the remaining allegations contained in Paragraph 186 of Plaintiffs'  
12 Complaint.

13 187. Ethicon denies the allegations contained in Paragraph 187 of Plaintiffs'  
14 Complaint.

15 188. Ethicon denies the allegations contained in Paragraph 188 of Plaintiffs'  
16 Complaint.

### 17 **RESPONSE TO "COUNT X:**

### 18 **GROSS NEGLIGENCE**

19 189. Ethicon incorporates by reference its responses to each and every allegation  
20 contained in Plaintiffs' Complaint.

21 190. Ethicon denies the allegations contained in Paragraph 190 of Plaintiffs'  
22 Complaint. Ethicon denies that Plaintiffs are entitled to any recovery or any form of relief  
23 whatsoever from Ethicon.

24 191. Ethicon denies the allegations contained in Paragraph 191 of Plaintiffs'  
25 Complaint.

26 192. Ethicon denies the allegations contained in Paragraph 192 of Plaintiffs'  
27 Complaint. Ethicon denies that Plaintiffs are entitled to any recovery or any form of relief  
28 whatsoever from Ethicon.

1 193. Ethicon denies the allegations contained in Paragraph 193 of Plaintiffs'  
2 Complaint. Ethicon denies that Plaintiffs are entitled to any recovery or any form of relief  
3 whatsoever from Ethicon.

4 **RESPONSE TO “COUNT XI:**  
5 **UNJUST ENRICHMENT”**

6 194. Ethicon incorporates by reference its responses to each and every allegation  
7 contained in Plaintiffs' Complaint.

8 195. Ethicon lacks sufficient knowledge or information to know whether Plaintiff  
9 Julie Cruz was treated with any of its products, and Ethicon denies that allegation.  
10 Ethicon admits only that it sold TVT-O for uses consistent with the packaging and  
11 labeling. Johnson & Johnson does not sell any product. Ethicon denies the remaining  
12 allegations contained in Paragraph 195 of Plaintiffs' Complaint.

13 196. Ethicon lacks sufficient knowledge or information to know whether Plaintiff  
14 Julie Cruz was treated with any of its products, and Ethicon denies that allegation.  
15 Ethicon denies the remaining allegations contained in Paragraph 196 of Plaintiffs'  
16 Complaint.

17 197. Paragraph 197 of Plaintiffs' Complaint makes no allegations against Ethicon  
18 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
19 without sufficient knowledge or information so as to form a belief as to the truth of the  
20 allegations contained in Paragraph 197 of Plaintiffs' Complaint, and, therefore, denies  
21 those allegations.

22 198. Paragraph 198 of Plaintiffs' Complaint makes no allegations against Ethicon  
23 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
24 without sufficient knowledge or information so as to form a belief as to the truth of the  
25 allegations contained in Paragraph 198 of Plaintiffs' Complaint, and, therefore, denies  
26 those allegations.

27 199. Ethicon denies the allegations contained in Paragraph 199 of Plaintiffs'  
28 Complaint.

1           200. Ethicon denies the allegations contained in Paragraph 200 of Plaintiffs'  
2 Complaint.

3                                   **RESPONSE TO "COUNT XII:**  
4                                   **LOSS OF CONSORTIUM"**

5           201. Ethicon incorporates by reference its responses to each and every allegation  
6 contained in Plaintiffs' Complaint.

7           202. Ethicon denies the allegations contained in Paragraph 202 of Plaintiffs'  
8 Complaint.

9                                   **RESPONSE TO "COUNT XIII:**  
10                                  **PUNITIVE DAMAGES"**

11           203. Ethicon incorporates by reference its responses to each and every allegation  
12 contained in Plaintiffs' Complaint.

13           204. Ethicon denies the allegations contained in Paragraph 204 of Plaintiffs'  
14 Complaint.

15           205. Ethicon admits that it sold and tested TVT-O for uses consistent with the  
16 packaging and labeling, and that it has been available for purchase in the United States  
17 including the State of California. Ethicon admits further that TVT-O is safe and effective  
18 for uses consistent with the packaging and labeling. Johnson & Johnson does not sell or  
19 test any product. Ethicon denies the remaining allegations contained in Paragraph 205 of  
20 Plaintiffs' Complaint.

21           206. Ethicon admits that it sold TVT-O for uses consistent with the packaging  
22 and labeling, and that it has been available for purchase in the United States including the  
23 State of California. Johnson & Johnson does not sell any product. Ethicon denies the  
24 remaining allegations contained in Paragraph 206 of Plaintiffs' Complaint.

25           207. Ethicon admits that it marketed and sold TVT-O for uses consistent with the  
26 packaging and labeling. Johnson & Johnson does not market or sell any product. Ethicon  
27 denies the remaining allegations contained in Paragraph 207 of Plaintiffs' Complaint.  
28

1           208. Paragraph 208 of Plaintiffs' Complaint makes no allegations against Ethicon  
2 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
3 without sufficient knowledge or information so as to form a belief as to the truth of the  
4 allegations contained in Paragraph 208 of Plaintiffs' Complaint, and, therefore, denies  
5 those allegations.

6           209. Paragraph 209 of Plaintiffs' Complaint makes no allegations against Ethicon  
7 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
8 without sufficient knowledge or information so as to form a belief as to the truth of the  
9 allegations contained in Paragraph 209 of Plaintiffs' Complaint, and, therefore, denies  
10 those allegations.

11           210. Paragraph 210 of Plaintiffs' Complaint makes no allegations against Ethicon  
12 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
13 without sufficient knowledge or information so as to form a belief as to the truth of the  
14 allegations contained in Paragraph 210 of Plaintiffs' Complaint, and, therefore, denies  
15 those allegations.

16           211. Paragraph 211 of Plaintiffs' Complaint makes no allegations against Ethicon  
17 and requires no response by Ethicon. To the extent a response is required, Ethicon is  
18 without sufficient knowledge or information so as to form a belief as to the truth of the  
19 allegations contained in Paragraph 211 of Plaintiffs' Complaint, and, therefore, denies  
20 those allegations.

21           212. Ethicon denies the allegations contained in Paragraph 212 of Plaintiffs'  
22 Complaint.

23           213. Ethicon denies the allegations contained in Paragraph 213 of Plaintiffs'  
24 Complaint. Ethicon denies that Plaintiffs are entitled to any recovery or any form of relief  
25 whatsoever from Ethicon.  
26  
27  
28



**RESPONSE TO “COUNT XIV:****DISCOVERY RULE, TOLLING, AND FRAUDULENT CONCEALMENT”**

214. Ethicon incorporates by reference its responses to each and every allegation contained in Plaintiffs’ Complaint.

215. Paragraph 215 of Plaintiffs’ Complaint makes no allegations against Ethicon and requires no response by Ethicon. To the extent a response is required, Ethicon denies the allegations contained in Paragraph 215 of Plaintiffs’ Complaint.

216. Ethicon denies the allegations contained in Paragraph 216 of Plaintiffs’ Complaint.

217. Paragraph 217 of Plaintiffs’ Complaint states a legal conclusion and requires no response by Ethicon. To the extent a response is required, Ethicon is without sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in paragraph 217 of Plaintiffs’ Complaint, and, therefore, denies those allegations.

218. Paragraph 218 of Plaintiffs’ Complaint states a legal conclusion and requires no response by Ethicon. To the extent a response is required, Ethicon denies the allegations contained in Paragraph 218 of Plaintiffs’ Complaint.

**RESPONSE TO “PRAYER FOR RELIEF”**

In response to the unnumbered WHEREFORE paragraph under the “Prayer for Relief” subsection of Plaintiffs’ Complaint, Ethicon denies that Plaintiffs are entitled to any recovery or any form of relief whatsoever from Ethicon. Ethicon denies any remaining allegations, including subparts (i.) – (v.).

Ethicon hereby demands a trial by jury.

Ethicon denies any and all allegations contained in Plaintiffs’ Complaint not specifically admitted hereinabove.

**DEFENSES****FIRST DEFENSE**

The Complaint fails to state a cause of action upon which relief can be granted.

**SECOND DEFENSE**

The Complaint fails to state a cause of action upon which relief can be granted due to lack of adequate product identification.

**THIRD DEFENSE**

Plaintiffs' claims are barred for lack of subject matter jurisdiction.

**FOURTH DEFENSE**

Plaintiffs' claims are barred for lack of personal jurisdiction.

**FIFTH DEFENSE**

The Complaint must be dismissed because Plaintiffs provided insufficient process.

**SIXTH DEFENSE**

The Complaint must be dismissed because Plaintiffs provided insufficient service of process.

**SEVENTH DEFENSE**

Plaintiffs may be barred from bringing some of the claims alleged in the Complaint because Plaintiffs may lack standing and/or capacity to bring such claims.

**EIGHTH DEFENSE**

Plaintiffs may have failed to join indispensable parties or real parties in interest necessary for the just adjudication of this matter.

**NINTH DEFENSE**

Venue in this Court is improper, and this matter should be dismissed on intra-state or interstate forum non conveniens grounds.

**TENTH DEFENSE**

Certain of Plaintiffs' claims and remedies and the defenses thereto are governed by the laws of a foreign jurisdiction or the laws of the United States.

**ELEVENTH DEFENSE**

Plaintiffs' alleged causes of action have been improperly joined under the applicable Rules of Civil Procedure and the laws of the applicable state.

**TWELFTH DEFENSE**

The improper joinder of Plaintiffs' alleged causes of action violate the procedural and substantive due process rights of Ethicon under the Constitutions of the United States of America and the applicable state, as well as the applicable Rules of Civil Procedure and the laws of the applicable state.

**THIRTEENTH DEFENSE**

The improper joinder of Defendants violates the procedural and substantive due process rights of Ethicon under the Constitutions of the United States of America and the applicable state.

**FOURTEENTH DEFENSE**

Ethicon is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute in California and any other state whose law is deemed to apply in this case.

**FIFTEENTH DEFENSE**

Ethicon specifically pleads as to Plaintiffs' fraud, fraud by concealment and negligent misrepresentation claims, all affirmative defenses available to Ethicon under the rules and statutes of California and any state whose law is deemed to apply in this case, and under any common law principles of California and any state whose law is deemed to apply in this case.

**SIXTEENTH DEFENSE**

Plaintiffs' claims are barred by the doctrine of federal preemption, as established by statute, including the preemption provision of the Medical Device Amendments, 21 U.S.C. § 360k(a), to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., and by state and federal case law, and are barred by the Supremacy Clause of the United States Constitution, because the product at issue are regulated by the U.S. Food and Drug Administration ("FDA") under the Medical Device Amendments, 21 U.S.C. § 360k, et seq., to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., and other federal statutes and regulations.

**SEVENTEENTH DEFENSE**

At all relevant times, Ethicon was in full compliance with all applicable federal statutes and regulations, including but not limited to the Medical Device Amendments, 21 U.S.C. § 360k, et seq., to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., and other federal statutes and regulations, and Plaintiffs' claims are accordingly barred.

**EIGHTEENTH DEFENSE**

Plaintiffs' claims against Ethicon are expressly and/or impliedly preempted by federal law, including but not limited to, the regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. See 21 U.S.C. § 301 et seq.; see also Fed. Reg. 3922 (Jan. 24, 2006).

**NINETEENTH DEFENSE**

Plaintiffs' claims are barred because Ethicon complied with all applicable state and federal statutes regarding the product at issue including the requirements and regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. In the event that Plaintiffs' claims are not barred, Ethicon is entitled to a presumption that the product at issue is free from any defect or defective condition as the plans or design for the product at issue or the methods and techniques of manufacturing, inspecting, and testing the product at issue were in conformity with government standards established for the industry that were in existence at the time the plans or designs for the product at issue or the methods and techniques of manufacturing, inspecting, and testing the product at issue were adopted.

**TWENTIETH DEFENSE**

Plaintiffs' claims are barred, in whole or in part, by the deference that federal and state constitutional law and federal and state common law give to discretionary actions by the FDA under the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301 et seq., and regulations promulgated there under.

**TWENTY-FIRST DEFENSE**

Plaintiffs' claims are governed and barred, in whole or in part, by Sections 2, 4, and 6 of The Restatement (Third) of Torts (including the comments thereto) because Ethicon complied with all applicable statutes and with the requirements and regulations of the FDA.

**TWENTY-SECOND DEFENSE**

Any claims by Plaintiffs relating to alleged communications with regulatory agencies in the United States government are barred in whole or in part by operation of applicable law, including the First Amendment rights of Ethicon to Complain to the government.

**TWENTY-THIRD DEFENSE**

Plaintiffs' claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under the law with determining the content of warnings and labeling for medical devices.

**TWENTY-FOURTH DEFENSE**

Plaintiffs cannot state a claim with regard to warnings and labeling for medical devices because the remedy sought by Plaintiffs is subject to the exclusive regulation of FDA.

**TWENTY-FIFTH DEFENSE**

Plaintiffs' claim for punitive damages is barred because the product(s) at issue were manufactured and labeled in accordance with the terms of FDA's clearance of the product(s) at issue.

**TWENTY-SIXTH DEFENSE**

Plaintiffs' claims are barred in whole or in part by Plaintiffs' failure to assert a safer design for the product(s) at issue.

**TWENTY-SEVENTH DEFENSE**

Plaintiffs' claims are barred in whole or in part because the product(s) at issue provided a benefit to users of such products and greatly outweighed any risk created by

1 using such product(s), any risk could not have been avoided through the use of the  
2 highest standards of scientific and technical knowledge available at the time, the benefit  
3 provided to users could not be achieved in another manner with less risk, and adequate  
4 warnings concerning the risk were provided.

5 **TWENTY-EIGHTH DEFENSE**

6 Ethicon made no express or implied representations or warranties of any kind to  
7 Plaintiffs, nor did Plaintiffs rely on any representations or warranties made by Ethicon to  
8 others.

9 **TWENTY-NINTH DEFENSE**

10 Any express or implied warranties alleged to have been made by Ethicon were  
11 disclaimed.

12 **THIRTIETH DEFENSE**

13 Ethicon did not make nor did it breach any express or implied warranties and/or  
14 breach any warranties created by law. To the extent that Plaintiffs relied on any theory of  
15 breach of warranty, such claims are barred by applicable law, by the lack of privity  
16 between Plaintiffs and Ethicon, and/or by Plaintiffs' failure to give Ethicon timely notice  
17 of the alleged breach of warranty and an opportunity to cure. Ethicon further specifically  
18 pleads as to any breach of warranty claim all affirmative defenses available to Ethicon  
19 under the Uniform Commercial Code, as enacted in the State of California or any other  
20 state whose law is deemed to apply in this case, and under the common law principles of  
21 California and any state whose law is deemed to apply in this case.

22 **THIRTY-FIRST DEFENSE**

23 To the extent that any of Plaintiffs' claims can be, or are construed as, alleging a  
24 violation of consumer protection laws, Ethicon specifically pleads all affirmative  
25 defenses available to Ethicon under the rules and statutes of California and any state  
26 whose law is deemed to apply in this case, and under the common law principles of  
27 California and any state whose law is deemed to apply in this case.  
28

**THIRTY-SECOND DEFENSE**

The injuries and damages allegedly suffered in this action, which are denied, were not foreseeable to Ethicon given the state of scientific knowledge and state-of-the-art at the time of the alleged injuries. At all times relevant, the product at issue conformed to state-of-the-art specifications and state-of-scientific knowledge for such products at that time, as well as all applicable statutes and regulations, including those of FDA.

**THIRTY-THIRD DEFENSE**

Plaintiffs knowingly and voluntarily assumed any and all risks associated with the use of the product at issue in this case and thus the “last clear chance” and assumption of the risk doctrines bar in whole or in part the damages that Plaintiffs seek to recover herein.

**THIRTY-FOURTH DEFENSE**

Plaintiffs’ claims are barred, in whole or in part, because Ethicon acted in good faith at all relevant times and gave adequate warnings of all known or reasonably knowable risks associated with the use of its product.

**THIRTY-FIFTH DEFENSE**

At all relevant times herein, the products in question were manufactured and distributed with proper warnings, information, cautions, and instructions in conformity with generally recognized and prevailing standards in existence at the time.

**THIRTY-SIXTH DEFENSE**

Plaintiffs’ inadequate warning claims are barred because the alleged risk of which Plaintiffs claim is open, obvious, and/or a matter of common knowledge.

**THIRTY-SEVENTH DEFENSE**

Plaintiffs’ claims are barred in whole or in part because the product at issue were consistent with and/or exceeded consumer expectations.



**THIRTY-EIGHTH DEFENSE**

Plaintiffs' claims are barred in whole or in part because the product at issue were at all times properly prepared, packaged, and distributed, and were not defective or unreasonably dangerous.

**THIRTY-NINTH DEFENSE**

Adequate and complete warnings and instructions were provided with the product at issue. The product at issue was neither defective nor unreasonably dangerous when used according to its Instructions for Use.

**FORTIETH DEFENSE**

At all relevant times, the warnings and instructions accompanying the product at issue were governed by and conformed with applicable federal statutes, rules and regulations; therefore, warnings and instructions relating to the products were presumptively adequate.

**FORTY-FIRST DEFENSE**

Plaintiffs' causes of action are barred by the learned intermediary doctrine.

**FORTY-SECOND DEFENSE**

Ethicon is not liable to Plaintiffs because the end users of the product(s) at issue, Plaintiff's physician(s), were sophisticated users of the product(s).

**FORTY-THIRD DEFENSE**

Ethicon states that the sole proximate cause of the injuries and/or damages alleged by Plaintiffs was the actions, omissions, or negligence of a person or persons, other than Ethicon, for whose actions, omissions, or negligence Ethicon is in no way liable. Plaintiffs are not, therefore, entitled to recover from Ethicon in this action. As to Plaintiffs or to any other entity or person whose conduct or intervening negligence resulted in the alleged injuries and/or damages of Plaintiffs, if any, Ethicon expressly pleads the doctrines of assumption of risk, contributory negligence, comparative fault and/or comparative negligence, as well as the provisions of any applicable comparative

1 fault and/or comparative negligence and/or contributory negligence statute, law or policy  
2 of California and any other applicable state.

3 **FORTY-FOURTH DEFENSE**

4 The injuries and damages allegedly suffered in this action, which are denied, may  
5 have been caused, in whole or in part, by Plaintiffs' own fault, which bars or  
6 proportionately reduces Ethicon's liability, if any, for Plaintiffs' alleged damages.

7 **FORTY-FIFTH DEFENSE**

8 Plaintiffs voluntarily and unreasonably chose to encounter known dangers.

9 **FORTY-SIXTH DEFENSE**

10 The liability of Ethicon, if any, for Plaintiffs' non-economic loss must be  
11 apportioned in accordance with the provisions of the law of California and any other  
12 applicable state.

13 **FORTY-SEVENTH DEFENSE**

14 In the event Ethicon is held liable to Plaintiffs, which liability is expressly denied,  
15 and any other co-defendants are also held liable, Ethicon is entitled to a percentage  
16 contribution of the total liability from said co-defendants in accordance with principles of  
17 equitable indemnity and comparative contribution and pursuant to any applicable  
18 contribution or apportionment statute, law or policy of the applicable states.

19 **FORTY-EIGHTH DEFENSE**

20 There is no causal relationship between Ethicon's conduct and the injuries and  
21 damages alleged by Plaintiffs in the Complaint.

22 **FORTY-NINTH DEFENSE**

23 At all times mentioned herein, Plaintiffs were negligent, careless and at fault and  
24 conducted themselves so as to contribute substantially to their alleged injuries, losses, and  
25 damages. Said negligence, carelessness and fault of Plaintiffs bars in whole or in part the  
26 damages which Plaintiffs seek to recover herein.

**FIFTIETH DEFENSE**

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the product at issue in this case, if any, were solely caused by and attributable to the abnormal, unforeseeable, unintended, unreasonable, and improper use or misuse which was made of said products.

**FIFTY-FIRST DEFENSE**

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the product at issue in this case, if any, were not legally caused by the product at issue, but instead were legally caused by intervening and superseding causes or circumstances.

**FIFTY-SECOND DEFENSE**

Plaintiffs' alleged injuries, losses, or damages attributable to the product at issue in this case, if any, were caused by the acts or omissions of third parties for which Ethicon has no legal responsibility. Therefore, Plaintiffs' recovery against Ethicon, if any, should be reduced pursuant to California Civil Code § 1431.2.

**FIFTY-THIRD DEFENSE**

Ethicon expressly denies any third party engaging in the acts alleged by Plaintiffs was acting as Ethicon's agent or servant, at the instruction of Ethicon, or within its control. Therefore, Plaintiffs' claims, to the extent they seek to recover for the acts or omissions of such third parties, are barred in whole or in part as a matter of law.

**FIFTY-FOURTH DEFENSE**

Plaintiffs' causes of action are barred because the injuries and damages allegedly suffered in this action, which are denied, were due to an allergic, idiosyncratic or idiopathic reaction to the product at issue in this case, or by an unforeseeable illness, unavoidable accident, or preexisting condition, and/or another unrelated medical, genetic or environmental condition, disease or illness, without any negligence or culpable conduct by Ethicon.

**FIFTY-FIFTH DEFENSE**

Plaintiffs' claims are or may be barred by their failure to comply with conditions precedent to their right to recover.

**FIFTY-SIXTH DEFENSE**

Plaintiffs' claims are barred, in whole or in part, by the doctrine of avoidable consequences.

**FIFTY-SEVENTH DEFENSE**

The claims of Plaintiffs may be barred, in whole or in part, from recovery, due to spoliation of evidence and the failure to properly preserve evidence necessary to the determination of the claim.

**FIFTY-EIGHTH DEFENSE**

Plaintiffs' claims against Ethicon are barred by the doctrines of equitable estoppel, laches, consent, waiver, informed consent, release, unclean hands, res judicata, and collateral estoppel. Additionally, if any plaintiff had or has filed bankruptcy during the relevant time period of the events alleged in the Complaint or files for bankruptcy at some point in the future, the claims of any such plaintiff may be "property of the bankruptcy estate" which should be prosecuted by the bankruptcy trustee rather than plaintiff, or, if not disclosed by plaintiff on the schedules and/or statement of financial affairs, may be barred by the doctrine of judicial estoppel.

**FIFTY-NINTH DEFENSE**

Some or all of Plaintiffs' claims may be barred by the statutes of limitations, prescription, and/or statutes of repose of California or any other applicable state, including but not limited to California Code of Civil Procedure §§ 335.1, 338(a), 338(d), and 361.

**SIXTIETH DEFENSE**

To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred by *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

**SIXTY-FIRST DEFENSE**

Plaintiffs' alleged damages, if any, are barred in whole or in part by Plaintiffs' failure to mitigate such damages.

**SIXTY-SECOND DEFENSE**

The sale, labeling and marketing of the product at issue in this litigation is not, and was not, likely to mislead or deceive the public.

**SIXTY-THIRD DEFENSE**

The product at issue was altered after the products left the control, custody and possession of Ethicon, and said alteration relieves Ethicon of any and all liability.

**SIXTY-FOURTH DEFENSE**

Any strict liability cause of action for relief is subject to the limitations set forth in Restatement (Second) of Torts, Section 402A, comment k.

**SIXTY-FIFTH DEFENSE**

Plaintiffs' claims are barred in whole or in part under Section 402A, comment j and k of the Restatement (Second) of Torts, and/or the Restatement (Third) of Torts: Products Liability, Sections 2, 4, and 6 and comments thereto. Adequate warnings and complete warnings were provided to Plaintiff's prescribing physician, and therefore, the product was not defective or unreasonably dangerous.

**SIXTY-SIXTH DEFENSE**

Plaintiffs' claims are barred, in whole or in part, to the extent Plaintiffs have released, settled, entered into an accord and satisfaction or otherwise compromised their claims by any means.

**SIXTY-SEVENTH DEFENSE**

Any recovery by Plaintiffs must be reduced or offset by all amounts paid, payable by, or available from collateral sources.

**SIXTY-EIGHTH DEFENSE**

Plaintiffs' Complaint fails to state a claim upon which relief can be granted as to costs, attorney's fees, expert fees, expenses, pre-judgment interest, post-judgment interest, refund, rescission, unjust enrichment, disgorgement or restitution.

**SIXTY-NINTH DEFENSE**

The Complaint fails to state facts sufficient to entitle Plaintiffs to an award of punitive damages.

**SEVENTIETH DEFENSE**

No act or omission of Ethicon was malicious, oppressive, willful, wanton, reckless, or grossly negligent, and therefore any award of punitive damages is barred.

**SEVENTY-FIRST DEFENSE**

Plaintiffs' claims for pain and suffering are barred because they violate Ethicon's rights to procedural and substantive due process and equal protection as guaranteed by the Constitutions of the United States and California.

**SEVENTY-SECOND DEFENSE**

The imposition of punitive or exemplary damages would violate Ethicon's constitutional rights, including but not limited to those under the due process clauses in the Fifth and Fourteenth Amendments to the Constitution of the United States, and the equivalent or correlative applicable provisions in the Constitutions, common law, public policy, applicable statutes and court rules of the applicable states to these amendments and the excessive fines clause in the Eighth Amendment to the Constitution of the United States and the double jeopardy clause in the Fifth Amendment to the Constitution of the United States. They would further violate Ethicon's rights to the extent that punitive damages awarded to any plaintiff are (1) imposed by a jury that is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of such a punitive damages award; is not adequately and clearly instructed on the limits on punitive damages imposed by the principles of deterrence and punishment; is not expressly prohibited from awarding punitive damages, or determining the amount of an

award thereof, in whole or in part, on the basis of invidious discriminatory characteristics, including the corporate status, wealth, or state of residence of defendant; or is permitted to award punitive damages under a standard for determining liability for such damages which is vague and arbitrary and does not define with sufficient clarity the conduct or mental state which makes punitive damages permissible; (2) are not subject to independent de novo review by the trial and appellate courts for reasonableness and the furtherance of legitimate purposes on the basis of objective legal standards and in conformity with the United States Constitution as amended or any applicable State constitution as amended; (3) imposed where state law is impermissibly vague, imprecise, or inconsistent; (4) subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount; or (5) imposed on the basis of anything other than Ethicon's conduct within the State where each plaintiff resides, or in any other way subjecting Ethicon to impermissible multiple punishment for the same alleged wrong.

### **SEVENTY-THIRD DEFENSE**

Ethicon specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards as applied to the state and federal courts of the applicable states under the Due Process Clause of the Fourteenth Amendment to the United States Constitution.

### **SEVENTY-FOURTH DEFENSE**

With respect to Plaintiffs' demand for punitive damages, Ethicon specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards that arise under *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatheman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and its progeny, as applied by the federal courts of appeals, together with all such standards applicable under any other state's law.



**SEVENTY-FIFTH DEFENSE**

Ethicon asserts the provisions of all applicable statutory caps on damages of any sort, including punitive, non-economic or exemplary damages, under the laws of California and any other applicable state.

**SEVENTY-SIXTH DEFENSE**

Ethicon specifically pleads as to Plaintiffs' claims for punitive damages, all affirmative defenses available to Ethicon under the rules and statutes of California and any state whose law is deemed to apply in this case, and under any common law principles of California and any state whose law is deemed to apply in this case.

**SEVENTY-SEVENTH DEFENSE**

Ethicon specifically pleads as to Plaintiffs' strict liability claims, all affirmative defenses available to Ethicon under the rules and statutes of California and any state whose law is deemed to apply in this case, and under any common law principles of California and any state whose law is deemed to apply in this case.

**SEVENTY-EIGHTH DEFENSE**

Ethicon specifically pleads as to Plaintiffs' negligence claims all affirmative defenses available to Ethicon under the rules and statutes of California and any state whose law is deemed to apply in this case, and under any common law principles of California and any state whose law is deemed to apply in this case.

**SEVENTY-NINTH DEFENSE**

Ethicon hereby gives notice that it intends to rely upon and incorporate by reference any affirmative defenses that may be asserted by any co-defendant in this lawsuit.

**EIGHTIETH DEFENSE**

Ethicon reserves the right to assert any additional defenses and matters in avoidance, which may be disclosed during the course of additional investigation and discovery.

**DEMAND FOR JURY TRIAL**

Ethicon demands trial by jury of all issues as triable as a matter of right.

WHEREFORE, Defendant Ethicon prays that:

(1) Plaintiffs take nothing by reason of the Complaint;

(2) The Complaint is dismissed in its entirety and that a Judgment against Plaintiffs and in favor of Ethicon is entered;

(3) Ethicon be awarded its costs and expenses; and

(4) This Court award Ethicon any other and general or specific relief as this Court may deem just and proper.

DATED: November 7, 2018

TUCKER ELLIS LLP

By /s/ Joshua J. Wes

Joshua J. Wes

Attorneys for Defendants

ETHICON, INC. and JOHNSON & JOHNSON

**CERTIFICATE OF SERVICE**

I declare that I am a citizen of the United States and a resident of Los Angeles, California or employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to the within action. My business address is Tucker Ellis LLP, 515 South Flower Street, Forty-Second Floor, Los Angeles, California 90071-2223.

On **November 7, 2018**, I served the following: **ANSWER AND DEFENSES OF DEFENDANT ETHICON, INC. TO PLAINTIFFS' FIRST AMENDED COMPLAINT; DEMAND FOR JURY TRIAL** on the interested parties in this action by:

- (X) **ELECTRONICALLY VIA ECF:** the above-entitled document to be served electronically through the United States District Court, Central District ECF website, addressed to all parties appearing on the Court's ECF service list. A copy of the "Filing Receipt" page will be maintained with the original document in our office.
- ( ) **BY MAIL:** By placing a true copy thereof enclosed in a sealed envelope(s) addressed as above, and placing each for collection and mailing on the below indicated day following the ordinary business practices at Tucker Ellis LLP. I certify I am familiar with the ordinary business practices of my place of employment with regard to collection for mailing with the United States Postal Service. I am aware that on motion of the party served, service is presumed invalid if postal cancellation date or postage meter date is more than one day after date of deposit or mailing affidavit.
- (X) I declare that I am employed in the office of the Bar of this Court at whose direction the service was made.

Executed on **November 7, 2018**, at Los Angeles, California

/s/ Britteena Stafford  
Britteena Stafford